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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/810,883	03/16/2001	David Thomas	TNX98-08-01	2201
26839	7590	06/03/2004	EXAMINER	
TANOX, INC. 10301 STELLA LINK HOUSTON, TX 77025			WEHBE, ANNE MARIE SABRINA	
			ART UNIT	PAPER NUMBER
			1632	

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/810,883

**Applicant(s)**

THOMAS ET AL.

**Examiner**

Anne Marie S. Wehbe

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 29-46 is/are pending in the application.
- 4a) Of the above claim(s) 45 and 46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 29-44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

Applicant's amendment and response received on 11/24/03 has been entered. Claims 1-28 have been canceled and new claims 29-46 have been entered. Claims 29-46 are currently pending in the instant application.

Newly submitted claims 45-46 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the original claims were directed to bispecific molecules with a first determinant that targets an ITAM and a second determinant that targets an ITIM, since IgE is not an ITAM, the bispecific molecules of claims 45-46 wherein the first determinant targets IgE do not correspond to the originally claimed subject matter.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 45-46 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 29-44 are currently under examination. An action on the merits follows.

Those sections of Title 35, US code, not included in this action can be found in the previous office action.

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The objection to the amendment filed on 6/15/01 under 35 U.S.C. 132 because it introduces new matter into the disclosure is withdrawn in view of applicant's argument that antibodies to FcεRII are disclosed in the specification. While the office does not agree that page 18 provides such disclosure, the examiner finds that page 20 does provide such description.

The amendment filed on 3/9/04 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: new claims 29-46 recite bispecific antibodies wherein a second determinant binds to an ITIM that is not KIR. The specification as originally filed does not mention KIR, and does not disclose excluding KIR from ITIM determinants useful in the instant invention.

Applicant is required to cancel the new matter in the reply to this Office Action.

### ***Claim Rejections - 35 USC § 112***

The rejection of claims 1-9, 14, and 18-19 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention, is withdrawn in view of applicant's cancellation of the claims. It is also noted that applicant's new claims are clearly directed to bispecific antibodies.

The rejection of claims 1-9, 14, and 18-19 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, is withdrawn in view of applicant's cancellation of the claims. It is also noted that applicant's new claims are clearly directed to bispecific antibodies.

The rejection of claims 1-9, 14, and 18-19 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn in view of applicant's cancellation of the claims. It is further noted that new claims 29-46 do not recite

### ***Claim Rejections - 35 USC § 102***

The rejection of canceled claims 1, 2, 7-9, 14, 24, and 26-27 under 35 U.S.C. 102(a) as being anticipated by EP 0 861 891 A1. (1998), hereafter referred to as Daeron et al, is maintained over new claims 29, 31, and 33-43. Applicant's amendments and arguments have been fully considered but have not been found persuasive in overcoming the instant grounds of rejection for reasons of record as discussed in detail below.

The applicant argues that the previous grounds of rejection over the canceled claims do not apply to the new claims because the claims as amended exclude KIR as the ITIM and Daeron et al. teaches that other ITIMs are different than KIR. In response, Daeron et al. teaches

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bispecific molecules which include bispecific antibodies that are capable of cross-linking a stimulatory ITAM receptor and a KIR or **KIR homologues such as gp49B1** (Daeron et al., pages 14-15, claims 1-15). A KIR homologue is not a KIR but a separate and distinct molecule. Daeron et al. further teaches that KIRs, gp49B1, and FcγRIIB contain ITIM domains and that cross-linking of ITAM and ITIM on a mast cell results in the modulation of TNF-α release (Daeron et al., page 14-15, especially claim 15). While Daeron et al. does teach that ITIM containing receptors such as KIRs, gp49B1 and FcγRIIB are all slightly different in their inhibitory properties, all three ITIM containing molecules in fact exert inhibition on effector cell functions when crosslinked with an ITAM such as FcεRI (Daeron et al., page 9 and pages 13-14). Thus, despite differences between the ITIM containing KIR, gp49B1 and FcγRIIB inhibitory receptors, Daeron et al. clearly teaches that cross-linking any of these ITIMs with an ITAM on an effector cell such as a mast cell results in inhibition.

Thus, by teaching all the limitations of the claims as written, Daeron et al. anticipates the instant invention as claimed. Therefore, the rejection of record is maintained over new claims 29, 31, and 33-43.

### ***Claim Rejections - 35 USC § 103***

The rejection of canceled claims 4 and 18 under 35 U.S.C. 103(a) as being unpatentable over EP 0 861 891 A1. (1998), hereafter referred to as Daeron et al. in view of Arm et al. (1997) J. Immunol., Vol. 159, 2342-2349, is maintained over new claims 32 and 44. Applicant's

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amendments and arguments have been fully considered but have not been found persuasive in overcoming the instant grounds of rejection for reasons of record as discussed in detail below.

Applicant's arguments regarding the teachings of Daeron et al. have been addressed in detail above. The applicant has not presented any arguments concerning the teachings of Arm et al. Therefore, for reasons of record as discussed in detail in the previous office action and above, the rejection of record over new claims 32 and 44 is maintained.

The rejection of canceled claim 3 under 35 U.S.C. 103(a) as being unpatentable over EP 0 861 891 A1. (1998), hereafter referred to as Daeron et al., in view of U.S. Patent No. 5,530,101 (1996), hereafter referred to as Queen et al., is maintained over new claim 30. The applicant has not presented any arguments regarding these grounds of rejection. Therefore, the rejection of record is maintained.

No claims are allowed.

Applicant's amendment necessitated any new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

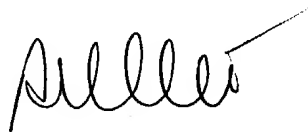
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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. The examiner can be reached Monday- Friday from 10:30-7:00 EST. If the examiner is not available, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. For all official communications, the technology center fax number is (703) 872-9306. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737.

Dr. A.M.S. Wehbé

**ANNE M. WEHBE' PH.D**  
**PRIMARY EXAMINER**

A handwritten signature in black ink, appearing to read 'Anne M. Wehbé', with a long horizontal line extending from the end of the signature.